

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-230 (GMS)
	)	
APOTEX, INC.	)	<b>JURY TRIAL DEMANDED</b>
	)	
Defendant.	)	

**STIPULATED PROTECTIVE ORDER**

**WHEREAS**, the parties to the above-captioned action (the "Action") may seek discovery of documents, information or other materials that may contain trade secrets or other confidential research, development or commercial information of other parties or third parties;

**NOW THEREFORE**, pursuant to Federal Rule of Civil Procedure 26(c), upon the stipulation and consent of the parties and for good cause shown, the Court hereby **ORDERS** that:

1. This Protective Order (the "Order") shall govern the disclosure and/or production of information, documents and tangible things in connection with the Action.
2. Each page of each document produced in discovery shall, to the extent practicable, bear a prefix identifying the producing party and a unique identifying number. Likewise, each discrete unit of each tangible item produced in discovery shall, to the extent practicable, also bear a prefix identifying the producing party and a unique identifying number.

3. Any producing person, entity or third party ("producing party") may designate any information, document or tangible item to be disclosed and/or produced as CONFIDENTIAL INFORMATION if: (a) the producing party claims in good faith that such information, document or tangible item comprises or contains trade secret or other confidential research, development or commercial information within the meaning of Federal Rule of Civil Procedure 26(c)(7); and (b) the producing party gives notice, as provided in this Order, that such information, document or tangible item comprises or contains CONFIDENTIAL INFORMATION.

a. All information, documents or tangible items to be produced in tangible form that the producing party wishes to designate as CONFIDENTIAL INFORMATION must, prior to production to the receiving party, be labeled by the producing party with the legend: **CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER**, or a suitable equivalent. The parties shall agree on how electronic data will be marked.

b. All information to be disclosed initially for inspection (such as for selection of materials for copying and production) that the producing party wishes to designate as CONFIDENTIAL INFORMATION must, prior to such disclosure, be specified in a writing provided to the receiving party (or orally, if followed by the necessary writing) that identifies the specified information as CONFIDENTIAL INFORMATION. All information to be disclosed orally (such as at a deposition) shall be automatically designated as CONFIDENTIAL INFORMATION for a period of thirty (30) days from the date the deposition transcript becomes available. Thereafter, the information contained in the deposition transcript will no longer be deemed

CONFIDENTIAL INFORMATION unless: (1) in a writing sent to counsel for the receiving party before the expiration of the thirty-day period, counsel for the producing party claims in good faith that the deposition transcript (or a specified portion of it) contains CONFIDENTIAL INFORMATION; or (2) at the deposition, counsel for the producing party stated on the record that certain portions of the deposition transcript contain CONFIDENTIAL INFORMATION.

4. In the event that a producing party believes access to particular information, documents(s) or tangible item(s) requested by the receiving party should be more limited than is provided in Paragraph 6 below, the producing party may additionally designate the information **CONFIDENTIAL ATTORNEYS' EYES ONLY**. Information appropriate for designation as CONFIDENTIAL ATTORNEYS' EYES ONLY shall presumptively include Investigational New Drug Applications, New Drug Applications, Abbreviated New Drug Applications, and related correspondence with the United States Food and Drug Administration ("FDA"), and pending patent applications. Disclosure of information designated CONFIDENTIAL ATTORNEYS' EYES ONLY shall be limited to persons identified in Subparagraphs 6a, 6d, 6e, 6f, 6g, and 6h below.

5. Any information, document or tangible item designated CONFIDENTIAL INFORMATION that is disclosed and/or produced in connection with this Action shall be maintained in strict confidence by the receiving party; shall be used solely in connection with this Action, subject to any further order of this Court regarding confidentiality; and shall not be disclosed to, or used by, any individual or entity except as permitted by this Order.

6. Access to CONFIDENTIAL INFORMATION shall be strictly limited to the following persons:

- a. Outside counsel for the receiving party, and the secretarial, clerical, paralegal and other supporting personnel of said outside counsel;
- b. When Merck & Co., Inc. is the receiving party, one (1) in-house legal or business person employed by Merck & Co., Inc., upon receipt by counsel for the producing party of a copy of the in-house legal or business person's completed and signed undertaking, and their secretarial, clerical, paralegal and other supporting personnel. Such person may not be directly involved in the prosecution of patent applications relating to pharmaceutical products. The in-house legal or business person shall be Gerard Devlin, Senior Attorney, Intellectual Property Litigation.
- c. When Apotex Inc. is the receiving parties, one (1) in-house legal or business person employed by Apotex Inc., upon receipt by counsel for the producing party of a copy of the in-house legal or business person's completed and signed undertaking, and their secretarial, clerical, paralegal and other supporting personnel. Such person may not be directly involved in the prosecution of patent applications relating to pharmaceutical products. The in-house legal or business person shall be Jack Kay, President of Apotex, Inc.
- d. Outside experts or consultants for the receiving party who are not (and shall not become) employees of a receiving party and who are retained in connection with the disputes between or among the parties to this Action, and their supporting personnel; provided that the disclosure of CONFIDENTIAL INFORMATION to any such expert or consultant shall be made only after:

(1) Counsel desiring to disclose CONFIDENTIAL INFORMATION to such an expert or consultant obtains a completed and signed undertaking in the form of Exhibit A attached hereto from the expert or consultant and forwards a copy of said completed and signed undertaking and the expert's or consultant's current curriculum vitae to counsel for the producing party; and

(2) Expiration of a period of ten (10) business days, commencing with the receipt by counsel for the producing party of a copy of the expert's or consultant's completed and signed undertaking and current curriculum vitae. During this period, counsel for the producing party may object in good faith to the disclosure of CONFIDENTIAL INFORMATION to this expert or consultant for cause, *e.g.*, an identified conflict of interest. If counsel for the producing party fails to object to such disclosure within the prescribed period, any objection to such disclosure shall be deemed waived, except as to a basis for objection that was not known and could not reasonably have been discovered within said ten-day period. In the event that a good-faith objection is made within the prescribed period, there shall be no disclosure of CONFIDENTIAL INFORMATION to the expert or consultant until there is an express written agreement of the parties or order of this Court removing the objection. The party seeking disclosure to an objected-to expert shall have the obligation to seek an order of the Court removing the objection;

e. Witnesses testifying during a deposition or at trial, if the witness is a current or former director, officer, or employee of the producing party, so long as (1) (a) such examination concerns CONFIDENTIAL INFORMATION that the witness authored or previously had access to or knowledge of, as demonstrated by the

CONFIDENTIAL INFORMATION itself or by foundation testimony during a deposition, hearing or trial, or (b) the witness was employed by the producing party during the relevant time and is reasonably believed to have had access to the CONFIDENTIAL INFORMATION, in which case, if the witness testifies that he or she did not author or previously have access to or knowledge of the CONFIDENTIAL INFORMATION, there shall be no further questioning of the witness on such CONFIDENTIAL INFORMATION, and (2) in the case of a former director, officer or employee, the witness agrees to be bound by, and signs a copy of the written assurance attached hereto as Exhibit A, unless the producing party otherwise agrees to the disclosure without such signed written assurance.

f. Non-technical trial consultants and graphics or design firms retained by outside counsel for the receiving party for the purpose of preparing demonstrative or other exhibits, including their supporting personnel;

g. Licensed court reporters and videographers employed in connection with this Action; and

h. This Court and its authorized personnel.

7. Subject to Paragraph 4, the designated in-house legal or business person of the receiving party shall be permitted to inspect and have access to all CONFIDENTIAL INFORMATION and to discuss such CONFIDENTIAL INFORMATION with any other person identified in Paragraph 6. However, the in-house legal or business person may retain copies of documents designated or containing CONFIDENTIAL INFORMATION of a producing party only in a location exclusively

within their control (e.g., in a secure office or in a locked file cabinet) or in a location that is controlled by outside counsel.

8. CONFIDENTIAL INFORMATION may be used, relied upon and referred to in any testimony or other evidence presented at any trial, hearing or deposition conducted in connection with this Action, so long as the person presenting such testimony or evidence is authorized to have access to such CONFIDENTIAL INFORMATION under the terms of this Order, and subject to any further order of this Court regarding confidentiality.

9. If the CONFIDENTIAL INFORMATION of a producing party is to be filed with this Court in connection with any proceeding in this Action, it shall be filed in a sealed envelope marked with the caption of the case and the following legend, or its equivalent:

**CONTAINS CONFIDENTIAL INFORMATION SUBJECT TO PROTECTIVE ORDER TO BE OPENED ONLY BY OR AS DIRECTED BY THE COURT**

10. Nothing in this Order shall bar or otherwise restrict any attorney from rendering advice to a party-client or, in the course thereof, relying upon his or her knowledge of CONFIDENTIAL INFORMATION; provided, however, that in rendering such advice the attorney shall not disclose any CONFIDENTIAL INFORMATION received from another party or third party to unauthorized persons.

11. A receiving party's acceptance of material designated CONFIDENTIAL INFORMATION by a producing party shall not constitute an admission, or create an inference, that the material is in fact confidential within the meaning of Federal Rule of Civil Procedure 26(c)(7). This Order shall not foreclose any party from moving for an order that materials designated CONFIDENTIAL

INFORMATION are not confidential within the meaning of Federal Rule of Civil Procedure 26(c)(7). Prior to bringing such a motion, however, the receiving party shall first request in writing that the producing party change or remove its confidentiality designation. If the producing party refuses to change its confidentiality designation within ten (10) business days from the request, the receiving party may move for an order changing or removing the designation. On such a motion, the producing party shall have the burden of proving that the material it designated CONFIDENTIAL INFORMATION embodies its trade secrets or other confidential research, development or commercial information within the meaning of Federal Rule of Civil Procedure 26(c)(7).

12. The disclosure and/or production of any information, document or tangible item without one of the designations provided by Paragraphs 3 or 4 of this Order shall constitute a waiver of any claim of confidentiality, except where such undesignated disclosure or production resulted from inadvertence or mistake on the part of the producing party and such inadvertence or mistake is brought to the attention of the receiving party promptly after its discovery. Along with the notice of such inadvertent or mistaken undesignated disclosure or production, the producing party shall provide properly designated documents and/or tangible items, if applicable. Upon receipt of such notice and properly designated documents and/or tangible items, if applicable, the receiving party shall substitute properly designated copies for those previously received and treat the information contained in or derived from said replaced documents and/or tangible items as CONFIDENTIAL INFORMATION.

13. Should any CONFIDENTIAL INFORMATION be disclosed by a receiving party to any person not authorized to have access to such information under this

Order, the receiving party shall: (a) use its best efforts to obtain the prompt return of any such CONFIDENTIAL INFORMATION and to bind such person to the terms of this Order; (b) within three (3) business days of the discovery of such disclosure, inform such person of the provisions of this Order and identify such person, and the inadvertently disclosed information, to the producing party; and (c) request such person to sign an undertaking in the form of Exhibit A attached hereto. If executed, the undertaking shall be served upon counsel of record for the producing party within three (3) business days of its receipt by the receiving party. The requirements set forth in this Paragraph shall not prevent the producing party from applying to the Court for further or additional relief.

14. Nothing in this Order shall be construed to require disclosure of information, documents or tangible things that counsel contends is protected from disclosure by the attorney-client privilege, the attorney work-product immunity or any other applicable privilege or immunity. A producing party may produce a redacted version of information, documents or tangible things that counsel contends is protected from disclosure by the attorney-client privilege, the attorney work-product immunity or any other identified applicable privilege or immunity, identifying where the privileged or immune material was redacted with the designation **RP** (Redacted-Privileged).

15. If a producing party inadvertently or mistakenly produces information, documents or tangible items in this Action that should have been withheld subject to a claim of attorney-client privilege or work product immunity, such production shall not prejudice such claim or otherwise constitute a waiver of any claim of attorney-client privilege or work product immunity for such information, provided that the producing party promptly makes a good-faith representation that such production was

inadvertent or mistaken and takes prompt remedial action to withdraw the disclosure upon its discovery. Within three (3) business days of receiving a written request to do so from the producing party, the receiving party shall return to the producing party any documents or tangible items that the producing party represents are covered by a claim of attorney-client privilege or work product immunity and were inadvertently or mistakenly produced. The receiving party shall also destroy all copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information; provided, however, that this Order shall not preclude the party returning such information from making a motion to compel production of the returned information on a basis other than a waiver because of its inadvertent production as part of a discovery production under this protective order. The producing party shall retain copies of all returned documents and tangible items for further disposition.

16. If the discovery process calls for the production of information, documents or tangible items that a party cannot produce because its disclosure would breach an agreement with a third party to maintain such information in confidence, the producing party shall, no less than ten (10) business days before the date scheduled for production, give written notice to the third party that its information is subject to discovery in this Action and provide the third party with a copy of this Order. At the same time such written notice is given to the third party, the producing party shall advise the putative receiving party of: (a) the fact that such notice has been given; (b) the type of information being withheld; and (c) the name and address of the third party. The requested information shall not be produced unless the third party so agrees or the requesting party secures a Court order compelling production.

17. The restrictions and obligations set forth in this Order relating to CONFIDENTIAL INFORMATION shall not apply to any information that: (a) the parties agree, or the Court rules, is already public knowledge; (b) the parties agree, or the Court rules, has become public knowledge other than by a disclosure by a receiving party; or (c) has come or hereafter comes into the receiving party's legitimate possession without any confidentiality restrictions and independently of the producing party. The restrictions and obligations set forth in this Order shall not prohibit discussions with any person or entity regarding any CONFIDENTIAL INFORMATION if said person or entity already has legitimate possession thereof.

18. In the event that a receiving party desires to provide access to CONFIDENTIAL INFORMATION to any person not entitled to such access under this Order, the receiving party shall first request in writing an agreement to do so from the producing party. If the producing party refuses to enter into such an agreement within ten (10) business days, the receiving party may move the Court for an order that such person be given access thereto. In the event that the motion is granted, such person may have access to CONFIDENTIAL INFORMATION after first signing an undertaking in the form of Exhibit A attached hereto, a copy of which shall be forwarded promptly to counsel for the producing party, or under such other conditions as the parties to this Action may agree or this Court may order.

19. This Order shall not prevent any party from applying to the Court for further or additional protective orders.

20. This Order shall survive the termination of this Action.

21. After final termination of this Action including any appeals, outside counsel identified in Subparagraph 6a for a receiving party may retain one archival copy of deposition transcripts, deposition exhibits, Court transcripts, Court exhibits, and other submissions to the Court, including any CONFIDENTIAL INFORMATION contained therein. Within thirty (30) days after final termination of this Action, including any appeals, all additional CONFIDENTIAL INFORMATION of a producing party (including without limitation the producing party's documents produced in the action with the designation CONFIDENTIAL INFORMATION), in the possession, custody or control of a receiving party - or in the possession, custody or control of any person allowed access to such information under Paragraph 6 of this Order- must be either: (a) returned to outside counsel for the producing party; or (b) destroyed and such destruction certified in writing to outside counsel for the producing party.

**AGREED:**

MORRIS, NICHOLS, ARSHT &  
TUNNELL, LLP

/s/ Mary B. Graham (#2256)

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**SO ORDERED** this \_\_\_\_\_ day of \_\_\_\_\_, 2007.

THE HONORABLE GREGORY M. SLEET

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**AGREEMENT TO BE BOUND BY STIPULATED PROTECTIVE ORDER**

I, \_\_\_\_\_, state that:

a. My home address is \_\_\_\_\_

b. My present employer is

and my present work address is

c. My present title, occupation or job description is

d. A copy of my curriculum vitae is attached hereto (if an expert or consultant).

e. I have read and understand the provisions of the Stipulated Protective Order entered in this action and I will comply with the provisions of that Stipulated Protective Order. I consent to be subject to the jurisdiction of this Court for enforcement of this Stipulated Protective Order.

f. I will hold in confidence and not disclose to anyone not qualified under the Stipulated Protective Order any CONFIDENTIAL INFORMATION, or any summaries, abstracts or indices of any CONFIDENTIAL INFORMATION, that is disclosed to me or that I prepare.

g. Upon conclusion of the above-captioned litigation, including appeal, I will return all CONFIDENTIAL INFORMATION – and any summaries, abstracts and indices thereof, and documents or materials that I received or prepared relating thereto – in my possession to outside counsel for the party for whom I was employed, retained or acted as witness.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: \_\_\_\_\_